IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

LLOYD BELL, individually and as Executor of the Estate of Betty Whitley Bell, Deceased, Plaintiff, v. AMERICAN INTERNATIONAL INDUSTRIES INC., et al., Defendants/Third-Party Plaintiff, v. THE NESLEMUR COMPANY, f/k/a THE NESTLE-LEMUR COMPANY, Third-Party Defendant.	)	17CV111 UNDER SEAL

ORDER

This matter is before the Court on a Motion to Intervene and Extend Protective Order [Doc. #256] brought by Northwell Health, Inc. ("Northwell"). Northwell, the employer and research sponsor of Plaintiff's expert witness, Dr. Jacqueline Moline, seeks to intervene for the limited purpose of protecting the confidentiality of participants in Dr. Moline's peer-reviewed publication "Mesothelioma Associated with the Use of Cosmetic Talc." As set out below, Northwell's motion will be denied.

"On timely motion, the court may permit anyone to intervene who . . . has a claim or defense that shares with the main action a common question of law or fact." Fed. R. Civ. P.

24(b)(1). Most courts have found that Rule 24(b) is an appropriate method for a non-Party to address the scope of a protective order. Small v. Ramsey, No. 1:10CV121, 2011 WL 13311479, at *1 (N.D.W. Va. June 28, 2011); Beckman Indus., Inc. v. International Ins. Co., 966 F.2d 470, 472-73 (9th Cir. 1992) (collecting cases from the First, Second, Fifth, Sixth, and Tenth Circuits); see also Wright & Miller, 7C Fed. Practice & Procedure § 1911 (noting that although "the language of Rule 24(b) appears directed toward intervenors who seek to become involved in the main action . . . . courts generally have interpreted their discretion under the rule broadly and have held that it can be invoked by nonparties who seek to intervene for the sole purpose of challenging confidentiality orders"). The Court will follow that general trend and consider Northwell's proposed intervention as properly brought under Rule 24(b).

The decision to grant a Motion to Intervene under Rule 24(b) is within the discretion of the Court. "In exercising its discretion, the court must consider whether the intervention will unduly delay or prejudice the adjudication of the original parties' rights." Fed. R. Civ. P. 24(b)(3). Furthermore, the Court must consider whether the motion is "timely." Fed. R. Civ. P. 24(b)(1). When intervention is sought for a limited purpose, as it is here, the above factors will be considered in light of that particular purpose.

In this case, Northwell seeks intervention for what it describes as "a narrow, yet critical, enlargement" of a Protective Order entered by the Court at a hearing on September 25, 2020 (Northwell's Br. [Doc. #259] at 7.) In September, the Court granted Plaintiff's Motion for Protective Order in part, barring discovery into the identity of 32 of the 33 participants in Dr. Moline's research study, but allowing discovery regarding the inclusion of Plaintiff Ms. Bell, with that information designated as confidential and limited to this case for discovery-related

purposes. Northwell now seeks to bar inquiry into "the identity of anonymous individuals referenced in Dr. Moline's Article, including whether Plaintiff was one of the research subjects." (Northwell's Br. at 7.) Northwell asserts that such questioning would be contrary to standards of research privacy and confidentiality that are widely followed in the medical community, embodied in Department of Health and Human Services regulations, and specifically contemplated by Northwell's Institutional Review Board ("IRB") when it approved Dr. Moline's study. (Northwell's Mot. [Doc. #256] at 2.) Defendant American International Industries, Inc. ("AII") contends that Northwell's Motion should be denied as moot because Plaintiff effectively removed Dr. Moline from the case by missing a Court-imposed deadline for her deposition. Alternatively, AII contends that Northwell's intervention is untimely and that its interests in the case are adequately represented by Plaintiff. (Def.'s Br. [Doc. #274] at 1-2.)

To the extent Northwell has an interest in this case, it is in barring Defendants from questioning Dr. Moline about the participants in her study, and particularly about any connection between Plaintiff and her study. However, the deadline for Plaintiff to present Dr. Moline for deposition has passed. By order dated December 8, 2020, the Court directed Plaintiff to make Dr. Moline available for deposition by January 7, 2021 or withdraw her as an expert witness [Doc. #252]. That deadline has passed, and Plaintiff has neither made Dr. Moline available nor moved this Court for an extension of the deadline. Therefore, it appears that Plaintiff has elected to withdraw her from the case, in which case Northwell's Motion to Intervene is moot.

Even if Plaintiff were to successfully move the Court to extend the deadline for Dr. Moline's deposition at this late date, the Court would have concerns with the timing of Northwell's Motion. In response to a subpoena, Northwell disclosed the identity of Ms. Bell as a participant in the Moline study in September 2020. That disclosure led to a flurry of filings that culminated in a telephonic hearing on September 25, 2020, where the Court determined that Ms. Bell's inclusion in the research study could be disclosed for purposes of this case to the extent Plaintiff continued to rely on Dr. Moline as an expert witness, with that information designated as confidential and limited to this case for discovery-related purposes. (Sept. 25 Hr'g Tr. [Doc. #206] at 8, 56-57, 59-60, 64, 70-71, 73, 76-77, 84, 87-89, 94-97.) Northwell was made aware of this dispute on September 18, 2020 through an email from defense counsel, [Doc. #274-7], yet chose not to intervene at that time. When considering the timeliness of a motion to intervene, "[a] reviewing court should look at how far the suit has progressed, the prejudice which delay might cause other parties, and the reason for the tardiness in moving to intervene." Gould v. Alleco, Inc., 883 F.2d 281, 286 (4th Cir. 1989). Northwell moved to intervene on December 23, 2020, three months after the hearing where Ms. Bell's identity as a study participant was at issue, six weeks after the close of discovery, and two weeks after the Court imposed a deadline for the deposition of Dr. Moline. Allowing intervention at this late stage would require the Parties to effectively relitigate issues the Court resolved in September, stall progression of the case, and potentially delay trial, which would prejudice the Parties. Northwell has not provided, and particularly given its awareness of the proceedings in September the Court does not see, any reason that would excuse the lateness. Therefore, even

if Plaintiff were to be granted an extension for the deposition of Dr. Moline, the Court would deny Northwell's proposed intervention as untimely.

Furthermore, even if the Court were inclined to excuse Northwell's untimeliness, its argument for extending the protective order fails on the merits. Northwell asks the Court to protect Dr. Moline from questioning about any connection between her research study and Plaintiff. Northwell's arguments that disclosure of Ms. Bell's participation as a study subject would conflict with federal policy, the IRB approval of Dr. Moline's study, and generally accepted norms of medical research are largely the same contentions raised by Plaintiff in September. (See Def.'s Br. at 11-13 (comparing arguments raised by Northwell now with those previously made by Plaintiff)). As it was in September, the Court is cognizant that "the ability to conduct probing scientific and social research supported by a population willing to submit to in-depth questioning" depends on the guarantee that the researcher will take steps to ensure confidentiality. Farnsworth v. Procter & Gamble Co., 758 F.2d 1545, 1547 (11th Cir. 1985). To that end, Congress and the Department of Health and Human Services have implemented a substantial body of law governing ethics and privacy in human-subjects research. See generally The Common Rule, 45 C.F.R. Subpart A; HIPAA Privacy Rule, 45 C.F.R. Parts 160, 164.

In consideration of these principles, the Court in September prohibited inquiry into the identities of 32 of the 33 participants in Dr. Moline's study, but allowed discovery of Ms. Bell's participation to the extent Plaintiff relied on Dr. Moline as an expert witness, with the information designated as confidential and limited to this case during the discovery phase of the case. The Court understood the need for research study participants to be ensured of

privacy, but the Court found that Ms. Bell, through bringing this suit over her exposure to asbestos and employing Dr. Moline as her expert witness, had placed her medical condition and records at issue and effectively consented to discovery that probed the validity of the study and disclosure of her participation. (Sept. 25 Hr'g Tr. at 62-63.) As noted by the Court, to allow Dr. Moline to testify as an expert on Plaintiff's behalf relying on an anonymized study that in fact included Plaintiff, and without allowing any inquiry in that regard, would raise significant concerns regarding misleading the fact finder and misrepresenting the evidence.[1]

Northwell's arguments, while they provide a different perspective than the Parties, do not change that ultimate analysis. Northwell's IRB approved Dr. Moline's study using an expedited review procedure. In order to grant expedited approval, the IRB had to find, among other things, that Dr. Moline's research "involve[d] no more than minimal risk to the subjects." 45 C.F.R. § 46.116(f)(3). HHS guidance says that expedited review

> may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

Office for Human Research Protections, OHRP Exedited Review Categories (1998), https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html (last updated Mar. 21, 2016). Northwell argues that "[i]f researchers and research institutions that are non-parties to litigation are required to

[1] As noted during the hearing, Dr. Moline is free to decide that she could not serve as an expert in a case where she has used that plaintiff's information in a research study on which she relies; that is a question for Dr. Moline to decide. But it creates too great a risk of misrepresentation or misleading of the factfinder for Dr. Moline to serve as an expert for Plaintiff and then rely on an anonymized research study when in fact the Plaintiff on whom she is opining is a subject of the research study on which she relies.

disclose the identity of anonymous research subjects, the result would be a chilling effect on the IRB process and the medical community." (Northwell's Br. at 8.) Effectively, Northwell says, if confidential information used by Dr. Moline is discoverable, the risk to privacy of participation in virtually any research study may be more than "minimal." If that is the case, the IRB expedited review process would become essentially a dead letter, forcing all research into a slower, costlier process for approval.

Given the facts of this case however, Northwell does not appear to have any remaining privacy interest in the fact of Ms. Bell's participation in Dr. Moline's study. In a medical research study, the interest in confidentiality belongs primarily to the study participant, not the researcher or sponsoring facility. For example, in Farnsworth v. Proctor & Gamble Co., 758 F.2d 1545 (11th Cir. 1985), the Centers for Disease Control ("CDC") agreed to release the names and contact information for 50 participants in a study of toxic shock syndrome when those participants consented to the release. The Court in Farnsworth acknowledged that "disclosure of the names and addresses of [nonconsenting] research participants could seriously damage" voluntary reporting and hinder scientific progress. Id. at 1547. However, despite having those concerns as to nonconsenting participants, the CDC freely turned over the identities of study subjects who had given their consent. In this case, Ms. Bell brought suit prior to her death, putting her medical condition and any exposure to asbestos at issue.[2]

[2] The Court notes that Ms. Bell's privacy interest in her medical records and study participation may have diminished since her death. See, e.g., Wessler v. U.S. Dep't of Justice, 381 F. Supp. 3d 253 (S.D.N.Y. 2019) (holding in the context of a FOIA request for medical records that "the death of the subject of personal information does diminish to some extent the privacy interest in that information, though it by no means extinguishes that interest" (quoting Schrecker v. U.S. Dep't of Justice, 254 F.3d 162, 166 (D.C. Cir. 2001))). In this case, because Ms. Bell consented to the release of her records, the Court need not analyze in depth the extent to which her privacy interest has diminished.

Plaintiff Lloyd Bell chose Dr. Moline as an expert witness, putting the validity of Dr. Moline's study at issue and entitling Defendants to discover information that would allow them to test it. Mr. Bell signed a release allowing for the "disclosure of all protected medical information" connected to this claim [Doc. #179-6]. Even following the Court's September Order making clear that Ms. Bell's participation would be discoverable in this litigation, Plaintiff continued to employ Dr. Moline as an expert witness. All of this indicates that Ms. Bell while alive, and her husband to date, have consented to disclosure of her participation in Dr. Moline's study for purposes of this case. Northwell recognized the validity of that consent itself, when it released information regarding Ms. Bell's participation in the study in response to the submission of her consent form. Because Plaintiff has consented, and because allowing Dr. Moline to testify as an expert for Plaintiff without disclosing or addressing Plaintiff's inclusion in the research study that is part of the basis for Dr. Moline's expert opinion risks misleading the jury, the Court would deny Northwell's motion on the merits even if the intervention were allowed.

The Court does not find that another hearing would be helpful, and the request for a hearing on the motion will also be denied.

The Court notes that there are several related Motions to Seal, consistent with the Court's prior determination that, at least during discovery, the identification of Ms. Bell as a participant could be sealed. That issue will be addressed further with the Parties, and any issues related to sealing can be further considered at that time. However, given the pre-trial nature of this matter related to discovery issues, the Court will allow the Motions to Seal related

to Northwell's Motion to Intervene and Extend Protective Order and will also temporarily file this Order under seal.

IT IS THEREFORE ORDERED that Northwell Health, Inc.'s Motion to Intervene and Extend Protective Order [Doc. #256] and Motion for Telephone Hearing [Doc. #285] are DENIED as set out above.

IT IS FURTHER ORDERED that the related Motions to Seal [Doc. #260, #272, #273, #299] will be GRANTED, and further that this Order will also be temporarily sealed, subject to further discussion with the Parties regarding the continued need for and appropriateness of sealing.

This, the 25th day of February, 2021.

/s/ Joi Elizabeth Peake
United States Magistrate Judge